

REMARKS***SUMMARY OF TELEPHONIC INTERVIEW WITH EXAMINER***

Applicants wish to thank Examiner Kim for the courtesy of the telephonic interview conducted on December 23, 2008 during which the Examiner indicated that the foregoing amendments to the claims would render the outstanding rejections moot. Applicants further note that during the telephonic interview, the Examiner indicated that the foregoing amendments would not require any further search.

AMENDMENTS TO THE CLAIMS

Claims 60, 61, 68, 70-72, 76 and 78-79 were pending in the instant application as of the issuance of the Final Office Action dated November 25, 2008. According to the foregoing amendments, claims 60 and 70 have been amended. Accordingly, after the amendments presented herein have been entered, claims 60, 61, 68, 70-72, 76 and 78-79 will remain pending in this application.

Support for the amendments to the claims may be found throughout the specification and in the claims as originally filed. Specifically, support for the amendments to claims 60 and 70 can be found throughout the specification at, for example, page 36, lines 3-25.

No new matter has been added by the amendments to the claims. The amendments to the claims should not be construed as an acquiescence to the validity of the outstanding rejections and were done solely in the interest of expediting prosecution and allowance of the claims. Applicants reserve the right to pursue the claims as previously pending and as originally filed in one or more further applications.

***REJECTION OF CLAIMS 60-61, 68, 70-72, 76 AND 78-79 UNDER
35 USC § 112, FIRST PARAGRAPH (NEW MATTER)***

The Examiner rejects claims 60, 61, 68, 70-72, 76 and 78-79 "under 35 U.S.C. 112, first paragraph, new matter, as failing to comply with the written description requirement." Specifically, the Examiner is of the opinion that

Claim 60 (Claims 61, 68 dependent therefrom) and Claim 70 (Claims 71-72, 76 and 78-79 dependent therefrom) recite the limitation of a buffer solution and an enzyme solution having 'about 28% PEG8000', 'about 0.1 M Na-acetate', 'about 0.1 M imidazole', 'pH of about 6.8', 'about 5 mM YbCl₃', 'about 5 mg/ml LTA4 hydrolase', 'about 10 mM

Tris-HCl', 'pH of about 8' and 'about 1 mM bestatin'. The recited constituents are disclosed in the specification, on page 36. However, the recited limitations for buffer and enzyme solutions with the term 'about' are not supported by the original disclosure. The applicant is advised to point out the support in the original disclosure or amend the instant claims.

Applicants respectfully disagree. Applicants submit that one skilled in the art would appreciate that Applicants were in possession of the claimed invention at the time of the filing of the above-identified application. Indeed, Applicants submit that the previously claimed subject matter was supported by the specification as originally filed and in accordance with MPEP 2163(I)(B), in which the standard for written description as not constituting an "in haec verba requirement" is set forth. Indeed, MPEP 2163(I)(B) makes clear that "newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."

Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the validity of the Examiner's rejections, Applicants have amended the pending claims to remove reference to the term "about," thereby rendering the foregoing rejection moot. Applicants respectfully request reconsideration and withdrawal of the foregoing rejection under 35 U.S.C. § 112, first paragraph.

***REJECTION OF CLAIMS 60-61, 68, 70-72, 76 AND 78-79 UNDER
35 USC § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION)***

The Examiner has further rejected claims 60-61, 68, 70-72, 76 and 78-79 under 35 U.S.C. § 112, first paragraph as allegedly "failing to comply with the written description requirement." Specifically, the Examiner is of the opinion that

the recited term 'about' and/or 'comprising' makes the instant method claims much broader than the crystallization conditions disclosed in the specification on page 36. Also, the recitation of the open term 'comprising' for a buffer solution and an enzyme solution is so broad as to encompass many additional compounds in the solutions.... The method of crystallization encompassed by the breadth of the claims is not adequately described because a singular chemical composition can crystallize differently based on the crystallization conditions, and the space group and unit cell dimensions of a crystal of any given chemical composition can only be determined by analyzing that crystal's X-ray diffraction... The method having crystallization condition to crystallize any protein comprising SEQ ID NO:1 in the presence of about 1 mM bestatin and any other composition added beside recited constituents in Claims 60 and 70 cannot be sufficiently

described by the instant disclosure of specification on page 36. Thus, in view of the teachings of the specification, one skilled in the art would recognize that Applicants were in possession of the full scope of claimed invention at the time of filing of the present application.

Applicants respectfully disagree. Applicants submit that in view of their discovery of a method for crystallizing the LTA₄ hydrolase, and further in view of the teachings of the specification, one skilled in the art would appreciate that Applicants were in possession of the invention as previously claimed at the time of filing of the present application. Indeed, Applicants submit that one skilled in the art would appreciate that Applicants were in possession of the claimed genus of crystallization conditions encompassed by the claims as previously pending based, at least in part, on the exemplification of crystallization set forth in the specification and, further, on the general knowledge at the time of filing of the present application.

Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the validity of the Examiner's rejections, Applicants have amended the pending claims in accordance with the Examiner's recommendation, to specifically recite the crystallization conditions set forth in the specification, and to remove recitation to the terms "about" and "comprising", thereby rendering the foregoing rejection moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims as lacking written description under 35 U.S.C. § 112, first paragraph.

***REJECTION OF CLAIMS 60-61, 68, 70-72, 76 AND 78-79 UNDER
35 USC § 112, FIRST PARAGRAPH (ENABLEMENT)***

The Examiner has further rejected claims 60-61, 68, 70-72, 76 and 78-79 under 35 U.S.C. § 112, first paragraph as lacking enablement. Specifically, the Examiner is of the opinion that

the specification, while being enabling for a method comprising crystallization of SEQ ID NO: 1 in the presence of bestatin by the condition described on page 36, lines 3-19, that results in a crystal having the space group P21212 and the unit cell dimensions $a=67.59 \text{ \AA}$, $b=133.51 \text{ \AA}$, $c=133.51 \text{ \AA}$ and $\alpha=\beta=\gamma=90^\circ$; does not reasonably provide enablement for a method comprising crystallization of SEQ ID NO: 1; wherein the crystallization is performed with any buffer solution as long as it contains about 28% PEG8000, about 0.1 M Na-acetate, about 0.1 M imidazole at a pH of about 6.8 and with

about 5 mM YbCl₃ as an additive; and any enzyme solution as long as it contains about 5 mg/ml LTA4 hydrolase comprising the amino acid sequence of SEQ ID NO:1 (i.e., any protein or fusion protein as long as it contains SEQ ID NO:1) in about 10 mM Tris-HCl at a pH of about 8, supplemented with about 1 mM bestatin; wherein the buffer solution and the enzyme solution can have any other additional constituents (e.g., compounds, molecules or proteins)...

The Examiner notes that instant amendments recite constituents of the buffer solution and the enzyme solution used in a method of crystallizing the protein of SEQ ID NO:1. Contrary to the Applicants' argument, the recited term 'about' and/or 'comprising' makes the instant method claims much broader than the crystallization condition disclosed in the specification on page 36. Also, the recitation of the open term 'comprising' for a buffer solution and an enzyme solution is broad to encompass any other additional compounds in the solutions. As previously noted..., methods of protein crystallization were well known in the art, but the ability to crystallize a given protein was, at the least, challenging to a skilled artisan as even minor alterations in the conditions of crystallization could result in altered crystal forms, crystals of sub-diffraction quality, or a lack of crystal growth.

Applicants respectfully disagree and submit that based on the teachings in Applicants' specification as well as the general knowledge available in the art at the time of the filing of the present application, one of ordinary skill in the art would be able to make and use the invention as previously claimed using only routine experimentation. Indeed, Applicants submit that in view of their discovery of a method for crystallizing the LTA₄ hydrolase, and further in view of the teachings of the specification, one skilled in the art would be capable of practicing the claimed invention without undue experimentation. Indeed, Applicants submit that one skilled in the art would be capable of identifying crystallization conditions falling within the scope of the previously claimed invention using only routine experimentation, particularly in view of the guidance and success of the experiments set forth in the present application.

Notwithstanding the foregoing, solely in the interest of expediting examination and in no way acquiescing to the validity of the Examiner's rejections, Applicants have amended the pending claims in accordance with the Examiner's recommendation, to remove recitation to the terms "about" and "comprising" and, further, to recite the space group and unit cell dimensions, thereby rendering the foregoing rejection moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of the pending claims as lacking enablement under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing remarks, reconsideration of the rejections and allowance of all pending claims is respectfully requested. If there are any remaining issues or if the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

The Commissioner is hereby authorized to charge any deficiency in the fees paid herewith, or credit any overpayment, to Deposit Account No. 12-0080, under Order No. PVZ-006USRCE, from which the undersigned is authorized to withdraw.

Dated: January 16, 2009

Respectfully submitted,

/Maneesh Gulati/

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